

REMARKS

I. The Claims are Not Obvious

The Examiner has rejected Claims 49-57 under 35 U.S.C. Section 103(a) as allegedly being unpatentable over Skurkovich et al. (US 5,888,511) in view of Starnes et al. (*J. Immunol.*, 1990, vol. 145, pp. 4185-4191) and further in view of Doherty et al. *J. Immunol.*, 1990, vol. 149, pp. 1666-1670). Applicant disagrees.

The Examiner admits that “Skurkovich et al does not teach treatment of a mammal having a plurality of symptoms of sepsis, and does not specifically teach treatment of a mammal exhibiting arterial hypotension.” (Office Action, page 2). In view of the weakness of the primary reference, Applicant submits that the current strategy employed by the Examiner to reject Claims 49-57 of the current Application was successfully traversed, as noted in the Office Action mailed August 29, 2000. Additionally, in a subsequent Office Action mailed November 25, 2005, the Examiner initially provided an indication of allowability for Claims 49-51. Upon the efforts of the Applicant to place the instant application in condition for allowance by canceling Claims 7-12, 15-18 and 34-48, the Examiner responded by providing a rejection under 35 U.S.C. Section 102(b) as allegedly being anticipated by United States Patent Number 5,888,511 to Skurkovich et al. This course of action is contrary to USPTO examination guidelines requiring the best references be provided to support an anticipation rejection (see 37 CFR 1.106(b)) and is suggestive of the Examiner’s reconstruction of the invention based on the references.

Without waiving this procedural argument, Applicant stresses the substantive argument that the Examiner has failed to consider rebuttal evidence. Applicant again directs the Examiner’s attention to the failure data in the Specification of the current Application. Applicant points to Table 3 in the Specification where: 1) anti-IFN- γ antibodies administered alone (60 minutes post challenge) failed to save any test animals; and 2) the combination of anti-TNF and anti-IFN- γ antibodies (administered 60 minutes post challenge) failed to save any test animals. Doherty showed decreased morbidity in test animals upon administration of anti-IFN- γ alone, which suggests the singular administration of anti-IFN- γ antibodies and not the co-administration of anti-IFN- γ antibodies with other anti-cytokine antibodies as disclosed by the Applicant. The Applicant achieved an unexpected result, however, and overcame the morbidity by administering the combination of anti-TNF antibodies, anti-IFN- γ antibodies and anti-IL-6 antibodies, as shown in Table 5. Applicant submits that the failure data in the instant

Specification underscores the non-obviousness of the present invention. The Examiner's rejection is thus unwarranted.

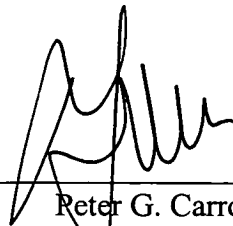
The Examiner is also asked to take note of the *degree of improved results* obtained with the combination (e.g. 100% survival in Table 5 in a "rescue from lethality" experiment). Evidence of unpredictable results that demonstrate *improved* performance over the prior art will overcome an assertion of obviousness. *United States v. Adams*, 383 U.S. 39 (1966) (cited recently with approval by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*). In *Adams*, the patentee had developed a battery that utilized magnesium and cuprous chloride. This battery demonstrated unpredicted and improved results as compared to batteries commonly used in the prior art comprised of zinc and silver chloride. The prior art did suggest, however, that magnesium could be used to replace zinc and cuprous chloride could be used to replace silver chloride. Nevertheless, in spite of the suggestions in the prior art, the United States Supreme Court ruled that the patentee's battery was nonobvious in light of the unpredicted and improved performance as compared to the batteries commonly used in the art. Thus, even in light of suggested combinations set forth in the prior art, an invention is not obvious if it demonstrates unpredictable and improved performance as compared to devices used in the art.

CONCLUSION

The Applicant believes that the arguments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicant encourages the Examiner to call the undersigned at 617.984.0616.

Respectfully submitted,

Dated: June 19, 2007



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